IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

C.R. BARD, INC., a New Jersey corporation, and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, Plaintiffs, v. MEDICAL COMPONENTS, INC., a Pennsylvania corporation, Defendant.	**MEMORANDUM DECISION AND ORDER GRANTING IN PART DEFENDANT'S PARTIAL MOTION FOR SUMMARY JUDGMENT** 2:12-cv-00032-RJS-DAO Chief District Judge Robert J. Shelby Magistrate Judge Daphne A. Oberg

In this patent infringement action, Plaintiffs C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, Bard) assert three patents against Defendant Medical Components, Inc. (MedComp). All three patents are directed to systems and methods for identifying a vascular access port as suitable for power injection following implantation of the device in the human body. Now before the court is MedComp's Motion for Partial Summary Judgment on the grounds of non-infringement and invalidity as to Bard's patents-in-suit.[1] For the reasons explained below, MedComp's Motion is GRANTED IN PART. The court defers consideration of MedComp's request for summary judgment on Bard's alleged infringement of MedComp's asserted patent.

BACKGROUND

Bard and MedComp are medical device manufacturers who develop, produce, and market various vascular access devices, including subcutaneous access ports. Access ports are devices

[1] Dkt. 463. In its Motion for Partial Summary Judgment, MedComp, as Counterclaimant, asserts its own U.S. Patent No. 8,021,324, seeking summary judgment against Bard for infringement. The court will not address MedComp's counterclaims in this Order.

that are implanted within the body of a patient, providing a convenient method of repeatedly delivering infusions of medicine, blood products, or other fluids into a patient's veins without requiring invasive surgical procedures or the need to start a new intravenous line on each occasion.[2] Power injection machines employing high pressure are sometimes used to deliver highly viscous fluids through access ports at specific desired rates of flow.[3] Unlike regular access ports that can fracture and cause significant bodily injury or death if subjected to power injection, special power injectable ports are designed to withstand high pressures.[4]

Generally, access ports offered by different manufacturers and different models exhibit substantially similar geometries, making it difficult to differentiate between power injectable ports and regular access ports once they have been implanted in the body.[5] Due to reported cases of injury, "the FDA cautioned medical providers in 2004 and 2005 that they should not use vascular access ports for power injection unless the ports were specifically and identifiably labeled for such use."[6] Access port manufacturers thus seek methods of adding identifiers to their ports that enable identification of power-injectability following implantation.[7] The various iterations of port identification methods comprise the heart of the patent disputes between Bard and MedComp.

Bard asserts three patents in this case: U.S. Patent Nos. 7,785,302 (the '302 Patent), 7,947,022 (the '022 Patent), and 7,959,615 (the '615 Patent).[8] The '302 Patent is the "parent"

[2] *See* Dkt. 585-2 (Bard's Redacted Tutorial Exhibit) at 4.

[3] *See id.* at 15–18.

[4] *See id.* at 20, 23–24.

[5] *See id.* at 26–27.

[6] *C R Bard Inc. v. AngioDynamics, Inc.*, 979 F.3d 1372, 1375 (Fed. Cir. 2020).

[7] *See* Dkt. 585-2 at 29–33; *see also* Dkt. 579 (Disk with MedComp's Technology Tutorial) at 26–30 (on file with Clerk's Office).

[8] Dkt. 463 at 1, ¶ 1.

patent, while the '615 Patent is a continuation and the '022 Patent is a continuation in part of the '302 Patent.[9] All three of the asserted patents are directed to systems and methods for venous access port identification.[10] The background and summary sections of the specifications in the '302 and '615 Patents are substantially similar,[11] and the detailed description sections of the specifications in the '302 and '022 Patents are also substantially similar.[12] Each of the independent and dependent claims in the '302 and '022 Patents require the presence of a type of radiopaque marker identifying the claimed port as power injectable.[13] And the claim at issue in the '615 Patent requires the presence of a structural feature identifying the claimed port as power injectable.[14]

The '302 and '022 Patents claim access ports wherein at least one radiopaque identifier is included in the port assembly, identifying the port as suitable for power injection. Regarding the '302 Patent, Bard asserts independent claims 1, 5, 8, and 10, and dependent claims 3, 4, 6, and 7, each dependent from either claim 1 or claim 5.[15] From the '022 Patent, Bard asserts independent claims 1 and 10, and dependent claims 3, 5, 8, 9, 12, and 14, each dependent from either claim 1 or claim 10.[16] Claim 1 of the '302 Patent is illustrative of these claims:

> 1. A venous access port assembly for implantation into a patient comprising:
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> a housing having a discharge port, a needle-penetrable septum, and a cap securable to the housing and retaining the septum securely in the assembly, the housing having a

[9] Dkt. 534 (Bard's Opposition to Partial Motion for Summary Judgment) at 7, ¶ 2. MedComp disputes that the '615 Patent is properly characterized as a continuation of the '302 Patent. *See* Dkt. 604 (MedComp's Reply). The court need not address this issue here as it is immaterial to the analysis at hand.

[10] *See* Dkt. 457-1 (Joint Appendix), JA-38 at 1:1-2; JA-101 at 1:1-2; and JA 148 at 1:1-2.

[11] *See id.* JA-38 at 1:13–2:24; JA-148 at 1:17–2:28.

[12] *See id.* JA-39 at 3:23–4:24; JA-101 at 2:63–3:62.

[13] *See id.* JA-43 at 12:56–14:21; JA-108 at 15:11–16:44.

[14] *See id.* JA-154 at 13:23–14:9.

[15] Dkt. 534 at 7, ¶ 3.

[16] *Id.*

housing base defining a bottom wall of at least one reservoir, and outwardly facing bottom surface,

the housing base including radiopaque alphanumeric characters that convey to a practitioner that the venous access port assembly is power injectable when an X-ray of the patient is taken after implantation.[17]

The '615 Patent claims access ports wherein at least one structural feature is included in the port assembly, identifying the port as suitable for power injection. Bard asserts independent claim 8 of the '615 Patent:

8. An access port for providing subcutaneous access to a patient, comprising:

a body defining a cavity accessible by inserting a needle through a septum, the body including a plurality of side surfaces and a bottom surface bounded by a bottom perimeter, the bottom surface on a side of the port opposite the septum, the bottom perimeter including a concave portion, the side surfaces including a first side surface through which an outlet stem extends; and

at least one structural feature of the access port identifying the access port as being power injectable subsequent to subcutaneous implantation, the at least one structural feature comprising at least one concave side surface in a second side surface different from the first side surface, the concave side surface extending to the bottom perimeter concave portion.[18]

PROCEDURAL HISTORY

On January 11, 2012, Bard filed the above-captioned action against MedComp, alleging infringement of the '302, '022, and '615 Patents.[19] At the same time, Bard also filed two similar infringement cases against AngioDynamics and Smiths Medical in this court.[20] These are known as the *Port I* cases. On December 17, 2012, the *Port I* actions were stayed and administratively closed while the patents-in-suit underwent *inter partes* reexamination before the United States

[17] Dkt. 457-1, JA-43 at 12:57–67.

[18] *Id.* JA-154 at 13:23–14:7.

[19] Dkt. 115 at 2–3.

[20] Dkt. 458 (Bard's Opening Claim Construction Brief) at 1. The case against AngioDynamics involves the same three Bard patents at issue in this case, and the case against Smiths involves two of the three patents. *See id.* at n.3.

Patent and Trademark Office (USPTO).[21] The stay remained in place for approximately seven years until it was lifted on October 4, 2019.[22] In November 2020, the AngioDynamics and Smiths Medical cases were transferred to the District of Delaware, but the instant MedComp action remained in Utah.[23]

In 2015, while the *Port I* actions were stayed, Bard filed a separate suit against AngioDynamics in the District of Delaware (*Port II*), alleging infringement of Bard's patents from a separate port patent family.[24] The patents at issue in *Port II* also claim strategies for identifying a power injectable port, specifically through the presence of radiographic markers.[25] On July 7, 2017, Bard filed a second infringement action against MedComp in the District of Utah (*Port III*).[26] That case, now pending before Judge Howard Nielson, involves Bard's patents from both the *Port I* and *Port II* patent families.[27]

Following the lifting of the stay in the *Port I* actions, this case has recommenced and progressed as follows: fact discovery commenced on March 30, 2020 and closed on February 8, 2021; the parties completed claim construction briefing on April 2, 2021; summary judgment briefing was completed on April 16, 2021; and the parties conducted a technology tutorial for the court on April 28, 2021.[28] After reviewing the claim construction briefs and cross-motions for

[21] *Id.* at 3–4.

[22] *See* Dkt. 161.

[23] *See* Dkt. 458 at 1 n.3.

[24] *Id.*

[25] *See AngioDynamics*, 979 F.3d at 1375.

[26] *See* Dkt. 458 at 1 n.3.

[27] *Id.*

[28] *See* Dkt. 539 (Bard's Opposition to MedComp's Motion to Consolidate Cases) at 2–3.

summary judgment, the court finds issues concerning the invalidity of Bard's patents-in-suit ripe for review.

LEGAL STANDARD

Summary judgment is appropriate when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."[29] A dispute is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party."[30] A fact is material if, under the governing substantive law, it could "affect the outcome of the suit."[31] When applying this standard, the court "view[s] the evidence and make[s] all reasonable inferences in the light most favorable to the nonmoving party."[32]

ANALYSIS

In its opening claim construction brief, MedComp argues that several of the claim terms in Bard's asserted patents are directed to printed matter and are, therefore, not entitled to patentable weight under the printed matter doctrine.[33] MedComp further argues that if the court adopts MedComp's proposed construction of the disputed terms and agrees the printed matter doctrine applies, the asserted Bard patent claims fail to meet the subject matter eligibility requirements of 35 U.S.C. § 101, rendering them invalid.[34] Based on these arguments, the Court will begin by analyzing whether the printed matter doctrine applies before turning to the discussion of subject matter eligibility and invalidity.

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[29] Fed. R. Civ. P. 56(a).

[30] *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

[31] *Id.*; *see also United States v. Simons*, 129 F.3d 1386, 1388 (10th Cir. 1997) ("The substantive law of the case determines which facts are material.").

[32] *N. Natural Gas Co. v. Nash Oil & Gas, Inc.*, 526 F.3d 626, 629 (10th Cir. 2008).

[33] *See* Dkt. 459 (MedComp's Opening Claim Construction Brief) at 11–17.

[34] *See* Dkt. 463 at 10–22.

I. The Printed Matter Doctrine

The Federal Circuit has long held that certain "printed matter" falls outside the scope of patentable subject matter as set forth in 35 U.S.C. § 101.[35] Although early cases employing this doctrine applied it to claims that literally encompassed "printed" materials, "the doctrine has evolved over time to guard against attempts to monopolize the conveyance of information using any medium."[36] Currently, the printed matter doctrine encompasses "any information claimed for its communicative content."[37] Thus, any "claim limitations directed to the content of information are not entitled to patentable weight because such information is not patent eligible subject matter" under § 101.[38]

Although printed matter is generally patent ineligible, there is a recognized exception to the rule: if a limitation claims printed matter that is "functionally related" to its "associated physical substrate," the printed matter is given patentable weight and may serve to distinguish the new invention from the prior art.[39] "The first step in the printed matter analysis is determining whether the limitation in question is in fact directed toward printed matter."[40] In other words, does the limitation in question claim the content of information? If so, "the next

[35] *See, e.g.*, *AngioDynamics*, 979 F.3d at 1381 (explaining that the Federal Circuit has "long recognized that certain 'printed matter' falls outside the scope of patentable subject matter under U.S. patent law"); *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1064 (Fed. Cir. 2010) ("This court has generally found printed matter to fall outside the scope of § 101")).

[36] *AngioDynamics*, 979 F.3d at 1381 (citing *Praxair Distribution, Inc. v. Mallinckrodt Hosp. Prod. IP Ltd.*, 890 F.3d 1024, 1032 (Fed. Cir. 2018) (extending the printed matter doctrine to claim limitations reciting certain mental steps or processes physicians take when prescribing a drug and finding the limitations were not entitled to patentable weight); *In re Distefano*, 808 F.3d 845, 849–50 (Fed. Cir. 2015) (citing cases developing the printed matter doctrine and providing examples of what qualifies as printed matter)).

[37] *Id.* (citing *Praxair*, 890 F.3d at 1032; *Distefano*, 808 F.3d at 848–49).

[38] *Praxair*, 890 F.3d at 1032.

[39] *Id.*; *see also AstraZenaca*, 633 F.3d at 1064.

[40] *Distefano*, 808 F.3d at 848.

step is to ascertain whether the printed matter is functionally related to its 'substrate.'"[41] For example, the Federal Circuit held in *In re Gulack* that although a sequence of printed digits on a wristband was printed matter, the sequence was still entitled to patentable weight[42] because "the printed matter and the circularity of the band were interrelated, so as to produce a new product useful for educational and recreational mathematical purposes."[43] In contrast, the Federal Circuit found that the printed matter in *AstraZeneca*, which merely added an FDA-required instruction sheet to a known drug product, was not sufficient to create a functional relationship and could not be given patentable weight.[44]

Here, MedComp identifies three claim limitations that it argues are printed matter: (1) "markings" ('302 Patent, claim 10), (2) "identification feature" ('022 Patent, claims 1, 3, 5, 8, 9, and 10), and (3) "structural feature of the access port identifying the access port as being power injectable" ('615 Patent, claim 8).[45] With respect to the "identification feature" and "markings," MedComp asserts that these terms fall squarely within the printed matter doctrine because they are "information conveyors" whose only purpose is to identify the port in question as capable of power injection.[46] Similarly, MedComp contends the "structural feature" described in the '615 Patent, which comprises at least one concave side surface of the port in question, serves the identical purpose of solely conveying information identifying the port as power injectable.[47]

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[41] *Praxair*, 890 F.3d at 1032.

[42] *See In re Gulack*, 703 F.2d 1381, 1386–87 (Fed. Cir. 1983).

[43] *In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004) (distinguishing *Gulack* from the printed matter under consideration in *Ngai*).

[44] *AstraZeneca*, 633 F.3d at 1065.

[45] *See* Dkt. 557 (Joint Claim Construction Chart) at 3–4.

[46] *See* Dkt. 459 at 13–14.

[47] *See id.* at 16.

In response, Bard contends that because the claims at issue in the '022 Patent require a "radiopaque identification feature" and the claims at issue in the '302 Patent require "radiopaque markings," the proposed claim limitations should be extended to include the terms "radiopaque markings" ('302 Patent) and "radiopaque identification feature" ('022 Patent).[48] Bard further argues that MedComp's proposed limitations "read the term 'radiopaque' completely out of the claims and therefore cannot be right."[49] If the term "radiopaque" is included, Bard maintains the claim limitations cannot be considered printed matter because the radiopacity of the marker/identification feature is merely a structural element, which makes the marker observable when viewed on X-ray, and does not specify the content of information.[50] Rather, the radiographic marker element "merely claims a technological way to convey information subcutaneously."[51]

Similarly, Bard argues the claim limitation concerning the '615 Patent—the structural feature identifying the port as being power injectable—is also not subject to the printed matter doctrine because the claimed structural feature is not directed to the content of information.[52] It is merely the means of conveying the information, and "[t]he fact that it eventually is used for identification does not make it any less of a structural feature."[53]

Both parties' arguments rely heavily on the Federal Circuit's recent decision in the *Port II* action, *C R Bard v. AngioDynamics*.[54] In that case, the Federal Circuit considered three

[48] *See* Dkt. 458 at 15, 17.

[49] *See* Dkt. 531 (Bard's Responsive Construction Brief) at 10.

[50] *Id.* at 11.

[51] *Id.* at 13.

[52] *Id.* at 19.

[53] *Id.*

[54] 979 F.3d 1372 (Fed. Cir. 2020).

similar Bard patents claiming strategies for identifying a power injectable port.[55] Each of the asserted claims at issue "require[d] the presence of a radiographic marker identifying the claimed port as power injectable."[56] The district court had considered the claim limitations "radiographic letters" and "visually perceptible information,"[57] holding "that the asserted claims were invalid because they were directed to printed matter as ineligible subject matter and were not inventive."[58] On appeal, the Federal Circuit agreed that the printed matter doctrine applied.[59] Because the asserted claims contained printed matter that was not functionally related to the remaining elements of the claims, the Federal Circuit found that the printed matter was not entitled to patentable weight.[60] However, upon continuing its analysis concerning the subject matter eligibility of the claims under § 101, the Federal Circuit found that the asserted claims retained patent eligibility because, when viewed as a whole, none of the claims were solely directed to the printed matter.[61]

Here, the parties disagree about the scope and meaning of the Federal Circuit's printed matter analysis in the *AngioDynamics* decision. Bard asserts "the Federal Circuit gave patentable weight to the radiopaque markers while separately holding that the content of the

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[55] *Id.* at 1375.

[56] *Id.*

[57] Prior to trial, the district court requested a report and recommendation from Magistrate Judge Fallon as to whether the terms "radiographic letters" and "visually perceptible information" were entitled to patentable weight under the printed matter doctrine. Judge Fallon found that the limitations were directed to the content of information and were not "functionally or structurally related" to the claimed ports, meaning the terms could not be entitled to patentable weight as they were printed matter. *See Bard Peripheral Vascular, Inc. v. AngioDynamics, Inc.*, No. CV 15-218-JFB-SRF, 2019 WL 1996022, at *3–6 (D. Del. Feb. 11, 2019). The district court adopted this recommendation. *AngioDynamics*, 979 F.3d at 1376.

[58] *AngioDynamics*, 979 F.3d at 1378 (citing *C R Bard Inc. v. AngioDynamics Inc.*, 382 F. Supp. 3d 332, 337–41 (D. Del. 2019)).

[59] *Id.* at 1381–82.

[60] *Id.*

[61] *Id.* at 1381, 1383–84.

information the markers conveyed was printed matter."[62] Bard supports this argument by pointing to the Federal Circuit's language from the case stating, "we hold that the content of the information conveyed by the claimed markers—i.e. that the claimed access ports are suitable for injection at the claimed pressure and flow rate—is printed matter not entitled to patentable weight."[63]

MedComp disputes Bard's characterization of the *AngioDynamics* decision, arguing that even though the Federal Circuit afforded no patentable weight to an element of the claim, it went on to examine the claims "as a whole" in order to determine whether the claimed subject matter was patent eligible under § 101.[64] Specifically, MedComp contends that the "proper analysis [under the printed matter doctrine] is that the element that imparts information is not entitled to patentable weight when the claim is viewed as a whole."[65] Based on this reading of *AngioDynamics*, MedComp here contends that it is not "the abstract information imparted by the element (*i.e.*, that the ports are power injectable) that is denied patentable weight." Rather, it is "the element itself" (the radiopaque identifiers or the structural feature of the port) that should be given no patentable weight.[66] The claim should then be "evaluated as a whole to determine whether there exists any new and unobvious functional relationship between the shape or markings and the port."[67]

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[62] Dkt. 531 at 11.

[63] Dkt. 458 at 5 (quoting *AngioDynamics*, 979 F.3d at 1382). Bard also identifies a later statement from the Federal Circuit's Anticipation analysis, where the court stated, "[W]hen evaluating the novelty and non-obviousness of claims, we must assign no patentable weight to the non-functional printed matter in the claims, which in this case is the information that the claimed access ports are suitable for injection at the claimed pressure and flow rate." *See id.* (quoting *AngioDynamics*, 979 F.3d at 1384).

[64] Dkt. 527 at 5 (quoting *AngioDynamics*, 979 F.3d at 1381).

[65] *Id.* (emphasis omitted).

[66] *Id.* at 6 (emphasis omitted).

[67] *Id.*

Before engaging the two-step printed matter analysis, the court must first address two preliminary questions presented by the parties' disputes. First, should the word "radiopaque" be included in the claim language at issue in the '302 and '022 Patents when considering the printed matter doctrine? And second, is printed matter restricted solely to the content of the information conveyed, or does it also encompass the medium used to convey the information? The court will answer the questions in turn.

A. The Term "Radiopaque" Must be Included in the Claim Limitation Language at Issue

As an initial matter, the court reiterates the current procedural posture of this case. The parties completed claim construction briefing on April 2, 2021. If construction of some of the proposed terms could be dispositive of the invalidity and/or infringement issues, Local Patent Rule 6.2 also requires the parties to submit "any motion for partial summary judgment on that issue . . . at the same time the moving party files its Cross-Motion for Claim Construction." Because MedComp asserts that certain of its proposed claim constructions, if adopted by the Court, will render some of Bard's asserted patent claims invalid, MedComp concurrently filed the instant Motion for Partial Summary Judgment.

"Although the determination of patent eligibility requires a full understanding of the basic character of the claimed subject matter, claim construction is not an inviolable prerequisite to a validity determination under § 101."[68] When the "basic character of the claimed subject matter in dispute . . . is clearly evident to the Court . . . no further construction of the claims is required."[69] Here, it is clearly evident to the court that all of the '302, '022, and '615 Patent

[68] *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat. Ass'n*, 776 F.3d 1343, 1349 (Fed. Cir. 2014) (citations omitted).

[69] *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat. Ass'n*, No. 12-2501 MAS TJB, 2013 WL 3964909, at *5 (D.N.J. July 31, 2013), *aff'd*, 776 F.3d 1343 (Fed. Cir. 2014).

claims at issue encapsulate the use of a feature—either a radiopaque marking/identifier or a structural feature including at least one concave side surface—which serves the purpose of conveying to a medical practitioner, subsequent to implantation, that the claimed access port is suitable for power injection. As such, the relevant claim terms at issue here, according to MedComp, are those that relate to the specific identification feature used in the claimed port: "markings" ('302 Patent), (2) "identification feature" ('022 Patent), and (3) "structural feature of the access port identifying the access port as being power injectable" ('615 Patent).

The court agrees with MedComp that these are the relevant terms to be considered. However, the court also agrees with Bard that "it cannot be right" to read the term "radiopaque" out of the proposed claim terms in the '302 and '022 Patents.[70] All of the asserted claims at issue in these two patents require a type of marking or identifier indicating that the claimed port is power injectable—but not just any type of marking or identifier. It must be "radiopaque," meaning that the marker/identifier is observable when viewed on X-ray after the port has been implanted in a patient's body. No other type of identifier is mentioned in the claims, and it would be erroneous for the court to omit the term "radiopaque" when construing these terms. Therefore, the court holds that the claim terms at issue for the '302 and '022 Patents are "radiopaque markings" and "radiopaque identification feature."

Because the court has not engaged in formal claim construction, "the Court must adopt a construction of the claims 'most favorable to the patentee[.]'"[71] Here, the court adopts Bard's

[70] Dkt. 531 at 10.

[71] *Content Extraction*, 2013 WL 3964909, at *5 (citing *Utramercial, Inc. v. Hulu, LLC*, 722 F.3d 1335, 1339–40 (Fed. Cir. 2013), *cert. granted, judgment vacated sub nom. WildTangent, Inc. v. Ultramercial, LLC*, 573 U.S. 942 (2014) (vacated on other grounds) ("At summary judgment, the district court may choose to construe the claims in accordance with this court's precedent, or if not it may choose to give a construction most favorable to the patentee, and to apply the usual rules pertaining to summary judgment from there, and still require clear and convincing evidence of ineligible subject matter.")).

proposed constructions as provided in Bard's Opening Claim Construction Brief: (1) "radiopaque identification feature" is "[a] feature that is opaque when viewed on an x-ray";[72] (2) "radiopaque markings" are "[m]arkings that are opaque when viewed on an x-ray";[73] and (3) "structural feature of the access port identifying the access port as being power injectable" is a "[s]tructural feature of the access port identifying that the claimed access port is power injectable."[74] However, the court makes clear that it is not adopting, at this time, Bard's contention that the printed matter doctrine does not apply to these terms. Such a determination requires further analysis.

As explained below, further claim construction is not required to resolve the portion of MedComp's Motion for Partial Summary Judgment directed to invalidity.

B. Printed Matter Encompasses the Medium Used to Convey Information

The roots of the printed matter doctrine date back to 1869 in *Ex Parte Abraham*, where the court found that coupons with various kinds of stamps and figures were not patentable subject matter.[75] The doctrine continued to evolve until the modern rule became fully developed in the 1931 case, *In re Russell*.[76] There, the court considered the claimed invention, which related to "improvements in indexes particularly to the indexing of names in directories," and held that "[t]he mere arrangement of printed matter on a sheet or sheets of paper . . . does not constitute any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement thereof . . . ." [77]

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[72] Dkt. 531 at 10.

[73] *Id.*

[74] *Id.* at 17.

[75] *See Distefano*, 808 F.3d at 849 (citing *Ex Parte Abraham*, 1869 C.D. 59 (Comm.Pat.1869)).

[76] *Id.* (citing *In re Russell*, 18 C.C.P.A. 1184, 48 F.2d 668, 669) (1931)).

[77] *Id.* (quoting *Russell*, 48 F.2d at 669).

Since 1931, both the Federal Circuit and its predecessor court "have consistently limited the printed matter rule to *matter* claimed for its communicative content."[78] After *Russell*, the following matter has been found to be printed matter: *markings* on meat "arranged in a certain manner for the purpose of identifying the meat,"[79] an FDA *label* providing the dosage instructions for using a medical product,[80] a *label* instructing a patient to take a drug with food,[81] *instructions* on how to perform a DNA test,[82] *numbers* printed on a wristband,[83] *markings* on dice communicating whether a player has won or lost a wager,[84] and the *mental step* requiring a medical provider to weigh the benefit of treating neonatal patients with inhaled nitric oxide.[85] Although this is not an exhaustive list, it is clear that "[t]he common thread amongst all of these cases is that printed matter must be *matter* claimed for what it communicates."[86]

Here, Bard argues the Federal Circuit in *AngioDynamics* "made clear that the radiopaque markers themselves, as opposed to the identification information conveyed by the markers, are

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[78] *Id.* (emphasis added).

[79] *In re McKee*, 20 C.C.P.A. 1018, 64 F.2d 379, 379–80 (1933).

[80] *See AstraZeneca*, 633 F.3d at 1064–65.

[81] *King Pharms., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1279 (Fed. Cir. 2010) ("Although these 'printed matter' cases involved the addition of printed matter, such as written instructions, to a known product, we see no principled reason for limiting their reasoning to that specific factual context. Rather, we believe that the rationale underlying these cases extends to the situation presented in this case, wherein an instructional limitation is added to a method, as opposed to a product, known in the art.").

[82] *See In re Ngai*, 367 F.3d 1336, 1338–39 (Fed. Cir. 2004).

[83] *See In re Gulack*, 703 F.2d 1381, at 1384–85 (Fed. Cir. 1983) (holding that even though the claim included printed matter, the printed matter was still entitled to patentable weight because there was a functional relationship between the printed matter and its underlying substrate).

[84] *In re Marco Guldenaar Holding B.V.*, 911 F.3d 1157, 1161 (Fed. Cir. 2018) ("The markings on Appellant's dice, however, constitute printed matter, as pointed out by the Board, and this court has generally found printed matter to fall outside the scope of § 101.").

[85] *Praxair*, 890 F.3d at 1033–34 ("Because claim limitations directed to mental steps may attempt to capture informational content, they may be considered printed matter lacking patentable weight . . . .").

[86] *Distefano*, 808 F.3d at 850 (emphasis added).

not printed matter."[87] Based on the Federal Circuit's own printed matter doctrine precedent, the court disagrees with this reading of the *AngioDynamics* decision.

As previously explained, "[t]he first step in the printed matter analysis is determining whether the limitation in question is in fact directed toward printed matter."[88] The court must examine whether the limitation claims the content of information. However, because the parties in *AngioDynamics* agreed that the asserted claims included printed matter, the Federal Circuit's analysis at the first step was limited.[89] The Federal Circuit explained that "[e]ach claim requires one or more markers 'identifying' or 'confirming' that the implanted access port is 'suitable' either 'for flowing fluid at a rate of at least 1 milliliter per second through the access port' or 'for accommodating a pressure with the cavity of at least 35 psi,' or both."[90] The court then went on to confirm that "[t]hese elements are directed to the content of the information conveyed."[91] It is unclear from this statement exactly which elements the Federal Circuit was referring to, nor is it clear which specific claim limitation was being analyzed because the parties already conceded that the claims included printed matter.

As this court sees it, the real disagreement over printed matter in *AngioDynamics* occurred at the second step of the printed matter analysis. Bard argued that the printed matter in the claims was functionally related to the power injectable port because the information conveyed by the markers provided new functionality by making the port "self-identifying."[92] The Federal Circuit disagreed with Bard's argument, citing past precedent and explaining that

[87] Dkt. 458 at 5.

[88] *Distefano*, 808 F.3d at 848.

[89] *See AngioDynamics*, 979 F.3d at 1381.

[90] *Id.* at 1382.

[91] *Id.*

[92] *Id.*

"as early as the 1930s, our predecessor court recognized that the mere marking of products, such as meat and wooden boards, with information concerning the product, does not create a functional relationship between the *printed information* and the substrate."[93] Based on this explanation and the Federal Circuit's reliance on previous decisions regarding the printed matter doctrine, this court disagrees with Bard's assertion that the *AngioDynamics* decision stands for the proposition that, when applying the printed matter doctrine, the content of the information conveyed can be divorced from the medium used to convey the information.

Indeed, the first step of the printed matter analysis explicitly requires a court to determine whether the claim limitation in question *is directed to* the content of information. The claim limitation is the "*matter* claimed for its communicative content" and is therefore linked to the content of the information because it is the medium through which the information is conveyed.[94] And as the Federal Circuit in *AngioDynamics* further explained, the matter claimed for its communicative content is not strictly limited to "printed" material, but instead encompasses "the conveyance of information using *any medium*."[95] Based on this reasoning, the court holds that printed matter includes not only the information being conveyed but the matter used to convey the information.

Although there are obvious similarities between *AngioDynamics* and the instant case, the facts and procedural posture are different. Unlike in *AngioDynamics*, where Bard agreed the claims included printed matter, here Bard insists that the asserted claim limitations are not

[93] *Id.* (citations omitted) (emphasis added). The *AngioDynamics* court also explained that "[a] conclusion that mere identification of a device's own functionality for purposes of the printed matter doctrine would eviscerate our established case law that 'simply adding new instructions to a known product' does not create a functional relationship." *Id.* (citing *AstraZeneca*, 633 F.3d at 1065 (citing *Ngai*, 367 F.3d at 1339)).

[94] *Distefano*, 808 F.3d at 850 (emphasis added).

[95] *AngioDynamics*, 979 F.3d at 1381.

printed matter at all because the structures at issue, which convey information, are distinct from the information conveyed.[96] Having found that this argument is not supported by Federal Circuit precedent, the court will now analyze whether the printed matter doctrine applies to this case.

C. The Asserted Claim Limitations Are Printed Matter

As previously explained, the court employs a two-step process to determine whether a claim limitation in question is printed matter. "The first step in the printed matter analysis is determining whether the limitation in question is in fact directed toward printed matter."[97] Federal Circuit cases "establish a necessary condition for falling into the category of printed matter: a limitation is printed matter only if it claims the content of information."[98] If this condition is met, "the next step is to ascertain whether the printed matter is functionally related to its 'substrate.'"[99]

Here, the claim limitations in question are "radiopaque markings" ('302 Patent), "radiopaque identification feature" ('022 Patent), and "structural feature of the access port identifying the access port as being power injectable" ('615 Patent). Both the radiopaque markings and radiopaque identification feature, which are observable on X-ray following subcutaneous implantation, convey to a medical practitioner that the access port is power injectable.[100] The '615 Patent uses a "structural feature," which includes at least one concave side surface, allowing a medical practitioner to identify a power-injectable port after implantation.

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[96] Dkt. 458 at 17. ("MedComp again improperly conflates the structure conveying information with the information conveyed to advance its printed matter argument.").

[97] *Distefano*, 808 F.3d at 848.

[98] *Id.*

[99] *Praxair*, 890 F.3d at 1032.

[100] *See, e.g.*, Dkt. 457-1, JA-44 at 14:17–21; JA-108 at 15:16–21.

Bard argues the radiopaque marking and identification feature elements are structural elements that do not specify the content of information.[101] They are simply "marker[s] that [are] observable when viewed on X-ray and can be used to convey information about an implanted access port."[102] But this statement from Bard's Responsive Claim Construction Brief about the ability of the markers to convey information generally is at odds with Bard's argument in its Opposition to MedComp's summary judgment motion. There, Bard clarified that "Bard's patents claim power injectable access ports that are identifiable as such after implantation."[103] Specifically, "the '302 and '022 Patent claims require power injectable access ports with a 'radiopaque alphanumeric message' that is opaque to radiation, so it is visible on an x-ray and indicates that the assembly is power injectable."[104]

Bard makes a similar argument regarding the structural feature claimed in the '615 Patent. Bard contends the structural feature is not directed to the content of information because it is merely the means used to convey information, and it is improper for the court to read a function into the structural element.[105] Yet, in its Opposition to summary judgment, Bard itself gives a function to the structural element, explaining that "[t]he '615 Patent claims a power injectable port with a structural feature—at least one concave side surface—that *identifies the port as power injectable*."[106]

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[101] *See* Dkt. 531 at 11.

[102] *Id.*

[103] Dkt. 534 at 2.

[104] *Id.* at 35 (citing *C.R. Bard v. AngioDynamics, Inc.*, 748 Fed. App'x. 1009, 1012) (Fed Cir. 2018) (internal quotation marks omitted)).

[105] Dkt. 531 at 19.

[106] Dkt. 534 at 36 (emphasis added).

Examining the claim language and reviewing Bard's own statements, it is evident that the claim limitations in question are directed to and claim the content of the information that a subcutaneously implanted port is suitable for power injection. The fact that the identification features at issue are a "technological way to convey information subcutaneously"[107] does not change this conclusion. Whether or not the limitations are technological structural features of the access ports, their sole function is to convey the information that the port is power injectable. Accordingly, the court finds that the claim limitations in question are printed matter.

Having so found, the court must proceed to the second step in the printed matter analysis and determine whether the printed matter should nevertheless be given patentable weight. In doing so, the court must "read the claim as a whole, considering each and every claim limitation."[108] Printed matter is only given patentable weight "if the matter is functionally or structurally related to the associated physical substrate[.]"[109]

Bard makes no argument that the radiopaque markers/identifiers and structural feature are functionally related to the underlying power injection port. And MedComp's argument against a functional relationship relies on the Federal Circuit's holding in *AngioDynamics* that "mere identification of a device's own functionality" is not "sufficient to constitute new functionality for purposes of the printed matter doctrine."[110]

Here, the court finds there is no functional relationship between the printed matter and the underlying power-injectable access port upon which it is printed. The printed matter does not change how the port works once it is implanted, it does not affect whether the port is capable of

[107] Dkt. 531 at 13.

[108] *Distefano*, 808 F.3d at 848.

[109] *Id.* at 851.

[110] Dkt. 459 at 15 (citing *AngioDynamics*, 979 F.3d at 1382).

power injection, and it does not interrelate with the port to produce a new and useful product. In other words, "the printed matter in no way depends on the [port], and the [port] does not depend on the printed matter. All that the printed matter does is [add a subcutaneous identifier to] an existing product."[111] For this reason, the court finds that the claim limitations in question are printed matter not entitled to patentable weight.

This means the court must address MedComp's argument that because the claim limitations in question are printed matter, MedComp is entitled to summary judgment of invalidity for all the asserted claims in which the limitations appear. The term "radiopaque identification feature" appears in asserted independent claims 1 and 10, and asserted dependent claims 3, 5, 8, and 9 of the '022 Patent; the term "radiopaque markings" appears in asserted independent claim 10 of the '302 Patent; and the term "structural feature . . ." appears in asserted independent claim 8 of the '615 Patent. However, rather than limit the validity analysis to only these claims, the court will expand its analysis to include all the remaining asserted independent and dependent claims in the '302 and '022 Patents. These include asserted independent claims 1, 5, and 8, and asserted dependent claims 3, 4, 6, and 7 of the '302 Patent, and asserted dependent claims 12 and 14 of the '022 Patent.

The reasons for the court's inclusion of the remaining claims are manifold. In conducting the printed matter analysis, the court naturally reviewed the specifications and all claim language from the asserted patents. In doing so, it became clear to the court that all the asserted claims contained limitations similar to the claim limitations the court has already found to be printed matter. For example, within the '302 Patent, independent claim 1 requires "radiopaque alphanumeric characters that convey to a practitioner that the venous access port assembly is

[111] *Ngai*, 367 F.3d at 1339.

power injectable when an X-ray of the patient is taken after implantation";[112] independent claim 5 requires "a radiopaque alphanumeric message observable through interaction with X-rays . . . and the alphanumeric message indicating that the assembly is power injectable;[113] and independent claim 8 requires "a radiopaque alphanumeric message . . . identifying the venous access port assembly as suitable for power injection."[114] The various dependent claims in both patents incorporate the port assembly described in the independent claims, including any radiopaque markings/messages and merely specify where or how such markings/messages are displayed.[115]

It is clear from the cited claim language that the radiopaque alphanumeric characters/messages serve the same purpose as the radiopaque markings/identification features: to convey to a medical practitioner, through a feature that is opaque to X-rays subsequent to implantation, that the port in question is power injectable. Having already resolved the question whether the printed matter doctrine applied to similar claim limitations, it would be illogical and tremendously inefficient for the court to ignore the obvious presence of printed matter in the other asserted claims. The radiopaque alphanumeric characters/messages in the remaining asserted claims are similarly directed to the content of information with no functional relationship to the underlying access port and constitute printed matter.

Moreover, the court is cognizant that, due to Local Patent Rules 4.1(b) and 6.2, the parties were artificially constrained as to what they could argue at the summary judgment stage.

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[112] Dkt. 457-1, JA-44 at 12:64–67.

[113] *Id.* at 13:14–18.

[114] *Id.* at 14:5–10.

[115] *See id.* at 13:3–7, 13:19–22; JA-108 at 16:13–14, 16:18–20. Although dependent claim 14 of the '022 Patent does not specify how or where the radiopaque identification feature is displayed, it incorporates the port assembly of independent claim 10, which includes a radiopaque identification feature on the bottom surface of the port.

Local Rule 4.1(b) restricts parties to no more than ten terms or phrases that may be presented to the court for claim construction. If the parties cannot agree on ten terms, as here, then five terms are allocated to the plaintiff and five to the defendant.[116] The parties must then decide how to allocate their five terms to address the most significant arguments and issues from their prospective. And under LPR 6.2, "[w]henever construction of a term may be dispositive of an issue, any motion for partial summary judgment must be filed at the same time the moving party files its Cross-Motion for Claim Construction." On its face, LPR 6.2 contemplates summary judgment based on the limited number of construed terms offered by the parties. Yet because the parties do not have the benefit of the court's construction of the proposed terms at this stage, they are required to file their motions for summary judgment without knowing how to precisely tailor their arguments. Here, the Local Patent Rules effectively prevented the parties from making more complete printed matter doctrine arguments.

Although the parties have not briefed the question of printed matter in all the asserted claims, the court finds that it is not necessary for them to do so as the arguments at issue will be identical to those already briefed by the parties. To conserve time and judicial resources,[117] the court holds that the printed matter doctrine applies to all the asserted claims in the '302, '022, and '615 Patents and will include them all in the following invalidity analysis.

II. Subject Matter Eligibility

The Patent Act, under 35 U.S.C. § 101, defines patent-eligible subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful

[116] *See* LPR 4.1(b).

[117] *See I/P Engine, Inc. v. AOL Inc.*, 576 F. App'x 982, 996 (Fed. Cir. 2014) (Mayer, J., concurring) ("From a practical perspective, there are clear advantages to addressing section 101's requirements at the outset of litigation. Patent eligibility issues can often be resolved without lengthy claim construction, and an early determination that the subject matter of asserted claims is patent ineligible can spare both litigants and courts years of needless litigation.").

improvement thereof." However, the Supreme Court has "long held that this provision contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable."[118] The Federal Circuit has confirmed that "where printed matter, irrespective of the material upon which it is printed, is the sole feature of alleged novelty, it does not come within the purview of [§ 101], as it is merely an abstract idea, and, as such, not patentable."[119]

Courts must "tread carefully" when considering whether a § 101 exception to patentability applies because "[a]t some level, 'all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.'"[120] Therefore, "an invention is not rendered ineligible for patent simply because it involves an abstract concept."[121] Such concepts remain eligible for patent protection if their application is directed "to a new and useful end."[122] To distinguish patents that claim abstract ideas from those that claim patent-eligible applications of those ideas, the Supreme Court has set forth a two-step framework for determining subject matter eligibility under § 101. This is known as the *Alice* inquiry.[123] At *Alice* step one, a court must decide whether the claims at issue, in their entirety, are directed to ineligible subject matter, such as an abstract idea.[124] "If not, the inquiry ends."[125] But if the claims are directed to an abstract idea, the court must then analyze the claims—both individually

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[118] *Alice Corp. Pry. V. CLS Bank Int'l*, 573 U.S. 208, 216 (2014) (quoting *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013)).

[119] *See AngioDynamics*, 979 F.3d at 1383 (citing *In re McKee*, 75 F.2d 991, 992 (C.C.P.A 1935)).

[120] *Alice*, 573 U.S. at 217 (quoting *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 71 (2012)).

[121] *Id.*

[122] *Id.* (internal quotation marks and citation omitted).

[123] The framework was first established in *Mayo*, but it was in *Alice* where the Supreme Court distilled *Mayo's* analysis into a distinct two-step process. *See Alice*, 573 U.S. at 217 (discussing *Mayo*, 566 U.S. at 77–82).

[124] *See Secured Mail Sols. LLC v. Universal Wilde, Inc.*, 873 F.3d 905, 909 (Fed. Cir. 2017) (citing *Alice*, 573 U.S. at 217).

[125] *Id.* (citations omitted).

and as an "ordered combination"—under *Alice* step two to determine whether they contain an "inventive concept" sufficient to "transform the nature of the claim into a patent-eligible application."[126]

Although the printed matter doctrine's "underlying rationale is in subject matter eligibility" under § 101, courts have typically applied the doctrine "in analyzing other patentability requirements, including novelty under 35 U.S.C. § 102 and nonobviousness under 35 U.S.C. § 103."[127] However, in *AngioDynamics*, the Federal Circuit confirmed that "a patent claim as a whole can be deemed patent ineligible" when a court analyzes a claim containing printed matter under the *Alice* inquiry.[128] But before a court may proceed to the *Alice* framework, the Federal Circuit added a preliminary inquiry for claims involving printed matter: "a claim may be found patent ineligible under § 101 on the grounds that it is [1] directed solely to non-functional printed matter and [2] the claim contains no additional inventive concept."[129] Following this directive, the court will now analyze the claims at issue here under what the court will refer to as the *AngioDynamics* framework.

A. The Claims at Issue are Directed Solely to Non-Functional Printed Matter and Contain No Additional Inventive Concept

The nearly identical specification language in the background section of the '302 and '615 Patents describes the purpose of conventional access ports—that they "provide a convenient method to repeatedly deliver a substance to remote areas of the body without utilizing surgical procedures"[130]—and their typical construction—a housing assembly, a septum, a reservoir, and

[126] *See Alice*, 573 U.S. at 217–18.

[127] *Praxair*, 890 F.3d at 1032 (citations omitted); *see also AngioDynamics*, 979 F.3d at 1383.

[128] *AngioDynamics*, 979 F.3d at 1383.

[129] *Id.*

[130] Dkt 457-1, JA-38 at 1:13–15; JA-148 at 1:17–19.

an outlet of the housing that communicates with a catheter which access a vein.[131] The specifications go on to explain that "once an access port is implanted, it may be difficult to determine the model, style, or design of the access port."[132] Therefore, "it would be advantageous to provide an access port which provides at least one identifiable characteristic that may be sensed or otherwise determined subsequent to subcutaneous implantation of the access port."[133] Likewise, the specification language of the '022 Patent also "relates to an access port having at least one perceivable or identifiable feature for identifying the access port, wherein the identifiable feature is perceivable after the access port is implanted within a patient."[134] It is clear from this language that the sole motivation of the patents at issue is providing some type of identifiable feature that communicates information about the underlying access port.

Following this general language, the claim language in each of the asserted patents then goes on the recite with specificity the exact type of identifiable feature and the exact information being communicated about the port in question. All the claims at issue in the '302 and '022 Patents require a type of radiopaque identifier conveying to a medical practitioner that the implanted port is power injectable. And the claim at issue in the '615 Patent requires a structural feature with at least one concave side, which also conveys that the implanted port is suitable for power injection.

When each claim is read as a whole, the focus of the claimed advance is using the above-named identifying features, in conjunction with an already known and typically constructed access port, to convey the information that the access port is power injectable. Bard disputes that

[131] *See id.* JA-38 at 1:20–24; JA-148 at 1:24–28.

[132] *Id.* JA-38 at 1:48–50; JA-148 at 1:52–54.

[133] *Id.* JA-38 at 1:54–57; JA-148 at 1:58–61.

[134] *Id.* JA-102 at 3:31–34.

the ports described in the asserted claims are typical or use conventional features, contending that each of the claims require a power injectable port, which was not a conventional feature as of the priority date of Bard's patents.[135] This argument is unpersuasive.

The various asserted claim language merely describes venous access port assemblies, including a housing or body with an outlet, a needle-penetrable septum, and a reservoir or cavity. There is nothing in the language of any of the asserted claims to specify what about these conventional features makes them capable of power injection. Bard's argument attempts to shift the focus away from the stated purpose of the asserted claims—identifying power-injectable ports subsequent to implantation—to the purported novelty of power-injectable ports. The court will not countenance this argument.

At the core of each of the asserted claims at issue here is the basic idea of using a specific type of identifier to convey information that a port is capable of power injection. The addition of merely novel yet nonfunctional printed matter identifiers does not change the fact that the focus of the claimed advance is solely on the content of the information conveyed. Any novelty in the implementation of this idea, through radiopaque features or concave surfaces, "is a factor to be considered only in the second step of the *Alice* analysis."[136] If the court were to find otherwise, it would undermine the rationale underlying the printed matter doctrine, which "guard[s] against

[135] *See* Dkt. 534 at 6.

[136] *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 715 (Fed. Cir. 2014).

attempts to monopolize the conveyance of information using any medium."[137] Accordingly, the court holds that the claims at issue are directed solely to non-functional printed matter. [138]

At the second step of the *AngioDynamics* framework, the court finds that the claims at issue contain no additional inventive concept beyond the claimed printed matter. As explained above, all the asserted claims recite only the assembly of a typical venous access port, including the conventional and known features described in the specification, coupled with a printed matter identifier conveying that the port is power injectable. Beyond the printed matter, there are no other elements that could be considered "inventive."

Having found that the claims at issue are directed solely to non-functional printed matter and contain no additional inventive concept, the court will proceed to the two-step *Alice* inquiry. Before doing so, however, the court must address Bard's argument that if the court were to find the identifiers at issue are printed matter, then the court cannot consider them in its validity analysis.[139] The court disagrees. When a court finds that a claim contains printed matter, it simply means that the printed matter is not given any patentable weight and may not be a basis for distinguishing prior art.[140] This is a concern when conducting § 102 novelty or § 103

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[137] *AngioDynamics*, 979 F.3d at 1381; *see also King*, 616 F.3d at 1279 ("The rationale behind this line of [printed matter doctrine] cases is preventing the indefinite patenting of known products by the simple inclusion of novel, yet functionally unrelated limitations."); *Ngai*, 367 F.3d 1336, 1339 (explaining that the court will not allow a party to continue patenting a product indefinitely simply because the party added a new instruction sheet to the already known product).

[138] The court recognizes that Federal Circuit decisions in the realm of patent law are binding authority, and the *AngioDynamics* decision is no exception to this rule. The court is also cognizant that this holding may appear in tension with the Federal Circuit's holding in *AngioDynamics* concerning whether similar claims are directed solely to printed matter. Crucially, the evidence and arguments before this court differ substantially from the evidence and arguments presented in *AngioDynamics*. Moreover, the Federal Circuit's decision in *AngioDynamics* provides this court and these parties the benefit of a clear framework for evaluating these issues that was not available to the trial court or the parties in *AngioDynamics* prior to the Federal Circuit's decision. At least in this court's view, the significant differences between the records compel a different result.

[139] *See* Dkt. 531 at 12. Bard argues that the Federal Circuit found the radiopaque markers in *AngioDynamics* were not printed matter because, otherwise, "they would not be entitled to patentable weight, and the Federal Circuit would not have considered them in its validity analysis."

[140] *See Distefano*, 808 F.3d at 848.

nonobviousness analyses. But determining whether a claim is directed to patent eligible subject matter under § 101 is a different matter. A validity analysis concerning whether a claim is directed to statutory subject matter is a "threshold test"[141] that "must precede the determination of whether that discovery is, in fact, new or obvious."[142] As such, "[t]he novelty and nonobviousness of the claims under §§ 102 and 103 does [sic] not bear on whether the claims are directed to patent-eligible subject matter under § 101."[143] The court must therefore look to the claim language in its entirety, including the printed matter, when conducting a validity analysis.[144]

B. The *Alice* Inquiry

"The validity of asserted claims under § 101 is a 'threshold inquiry' for the court to decide as a matter of law."[145] As previously explained, when determining subject matter eligibility under § 101, courts must follow the two-step framework established by the Supreme Court in *Alice*. "[A] claim falls outside § 101 where (1) it is directed to a patent-ineligible concept, *i.e.*, a law of nature, natural phenomena, or abstract idea, and (2), if so, the particular elements of the claim, considered both individually and as an ordered combination, do not add enough to transform the nature of the claim into a patent eligible application."[146] The first step of the inquiry examines "the focus of the claims, their character as a whole," and the second step

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[141] *Bilski v. Kappos*, 561 U.S. 593, 602 (2010) ("The § 101 patent-eligibility inquiry is only a threshold test.").

[142] *Parker v. Flook*, 437 U.S. 584, 593 (1978).

[143] *Two-Way Media Ltd. v. Comcast Cable Commc'ns, LLC,* No. CV 14-1006-RGA, 2016 WL 4373698, at *4 (D. Del. Aug. 15, 2016), *aff'd*, 874 F.3d 1329 (Fed. Cir. 2017).

[144] *See Two-Way Media Ltd. v. Comcast Cable Commc'ns, LLC*, 874 F.3d 1329, 1337 (Fed. Cir. 2017) ("Under *Alice* step one, the claims are considered in their entirety to ascertain whether their character as a whole is directed to excluded subject matter.") (internal quotation marks and citation omitted)).

[145] *Two-Way Media*, 2016 WL 4373698, at *3.

[146] *Elec. Power Grp., LLC v. Alston S.A.*, 830 F.3d 1350, 1353 (Fed. Cir. 2016) (citing *Alice*, 573 U.S. at 217–18) (internal quotation marks omitted).

looks "more precisely at what the claim elements add—specifically, whether . . . they identify an inventive concept in the application of the ineligible matter to which (by assumption at stage two) the claim is directed."[147]

1. *Alice* Step One

Under *Alice* step one, the court must "consider the claims in their entirety to ascertain whether they are directed to patent eligible subject matter."[148] Here, all the asserted claims are directed to using a specific identifier—either a radiopaque identifier or a structural element including at least one concave side—to communicate information to a medical practitioner that the access port in question is power injectable subsequent to implantation.

This case is similar to the Federal Circuit's recent decision in *Secured Mail*. There, the Court analyzed multiple patents involving "methods whereby a sender affixes an identifier, [an Intelligent Mail Barcode, a QR code, or a Personalized URL], on the outer surface of a mail object . . . before the mail object is sent."[149] Once the object is mailed, "[c]omputers and networks are used to communicate the information about the mail object's contents and its sender after the mail object is delivered."[150] The Court observed the claims were "not directed to an improvement in computer functionality," nor were they "directed to a new barcode format [or] an improved method of generating or scanning barcodes."[151] There was also "no description of how the unique identifier was generated."[152] The Federal Circuit ultimately concluded the

[147] *Id.* (internal quotation marks and citations omitted).

[148] *Secured Mail*, 873 F.3d at 909.

[149] *Id.* at 907.

[150] *Id.*

[151] *Id.* at 910.

[152] *Id.*

methods asserted in the claim language were directed solely "to the abstract process of communicating information about a mail object using a personalized marking."[153]

The same is true here. All the asserted claim language from the three patents at issue requires an identification feature that is incorporated into the underlying access port, which then communicates information about the port's capability to withstand power injection. The claims are not directed to an improvement in port technology—the port will function in exactly the same manner whether the identifier is present or not—and there is no description in the claim language describing how the radiopaque identifiers or concave side surfaces are generated. The claims are also void of any discussion of the X-ray technology used to view the radiopaque identifiers after implantation of the port, meaning the claims are not directed to determining if certain radiopaque identifiers or their placement on the port improves their visibility when subject to X-ray.

The specification language in the '302 and '615 Patents alludes to the difficulty of determining the model of the access port once it has been implanted and states that "such uncertainty may be undesirable, at least for replacement timing purposes, among other reasons."[154] The specification then goes on to explain that "it would be advantageous to provide an access port" with "at least one identifiable characteristic" that may be sensed or determined following implantation of the port.[155] But this is not enough to render the subject matter of the asserted claims patent eligible. Not only is this problem-solving language not included in any of

[153] *Id.* at 911.

[154] *See* Dkt. 457-1, JA-38 at 1:48–51; JA-148 at 1:52–55.

[155] *Id.* JA-38 at 1:54–57; JA-148 at 1:58–61.

the asserted claims, but the Federal Circuit has also clarified that "[t]he fact that an identifier can make a process more efficient . . . does not necessarily render an abstract idea less abstract."[156]

The Federal Circuit explicitly held in *Secured Mail* that the process of communicating information using a marking or identifier that does not functionally improve any aspect of the underlying object or identification process is an abstract idea not directed to patent eligible subject matter.[157] Because each asserted claim at issue here requires the use of an identifier to communicate information about the power injectability of the underlying port and provides no functional improvement to the port itself or the X-ray technology used to view the radiopaque identifiers, the court finds the claims are directed to an abstract idea.

2. *Alice* Step Two

At *Alice* step two, a court must "consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent eligible application."[158] The second step of the *Alice* inquiry "is satisfied when the claim limitations involve more than performance of well-understood, routine, and conventional activities previously known in the industry."[159] "[W]hether a claim recites patent eligible subject matter is a question of law which may contain underlying facts."[160] Determining whether a claim element "is well-understood, routine, and conventional to a skilled

[156] *Secured Mail*, 873 F.3d at 910.

[157] *Id.* at 910–11.

[158] *Alice*, 573 U.S. at 217 (quoting *Mayo*, 566 U.S. at 78–79); *see also Electric Power*, 830 F.3d at 1354 (explaining that under *Alice* step two, a court must scrutinize the claim elements "microscopically" to determine whether there is anything in the claims to render their subject matter patent eligible).

[159] *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1367 (Fed. Cir. 2018) (internal quotation marks, internal alteration, and citations omitted).

[160] *Id.* at 1368.

artisan in the relevant field is a question of fact."[161] "Any fact . . . that is pertinent to the invalidity conclusion must be proven by clear and convincing evidence."[162]

The court will begin the *Alice* step two analysis by scrutinizing the asserted claims in the '302 and '022 Patents before turning to the single asserted claim in the '615 Patent.

a. The Asserted Claims in the '302 and '022 Patents Do Not Contain an Inventive Concept

The specification for the '302 Patent explains that "the instant disclosure relates to an access port having at least one perceivable or identifiable feature for identifying the access port, wherein the identifiable feature is perceivable after the access port is implanted within a patient."[163] One example of the "information of interest" communicated by the identifiable feature is that the "access port may be correlative with the access port being power injectable."[164] The specification then describes one embodiment of an access port, in which "at least one identifiable feature may be perceived via x-ray or ultrasound imaging."[165] Likewise, the specification for the '022 Patent contains nearly identical language[166] and also teaches an embodiment where "at least one identifiable feature may be perceived via x-ray or ultrasound imaging."[167]

"The improvements in the specification, to the extent they are captured in the claims, create a factual dispute regarding whether the invention describes well-understood, routine, and

[161] *Id.*

[162] *Id.*

[163] Dkt. 457-1, JA-39 at 3:60–64.

[164] *Id.* at 4:5–10.

[165] *Id.* at 4:20–21.

[166] *See* Dkt. 457-1, JA-102 at 3:31–34, 42–44.

[167] *Id.* at 3:58–59.

conventional activities."[168] The court must therefore analyze the asserted claims "more microscopically"[169] to determine whether they capture the stated improvements.[170]

Here, the parties do not dispute that the alleged improvements to port identification are captured in the asserted claims. Indeed, it is clear from the claim language that each independent and dependent claim at issue requires the inclusion of some type of radiopaque identifier, perceivable via x-ray, conveying to a medical practitioner the information that the access port is power injectable. What the parties dispute is whether use of radiopaque identifiers "on implantable medical devices" was "well-understood, routine and conventional at the relevant time[.]"[171]

MedComp provides numerous pieces of evidence supporting its argument that radiopaque identifiers were well-understood, routine, and conventional to those skilled in the art of implantable medical devices. To begin, MedComp contends the "conventionality of radiopaque marking" can be found in Bard's own representations.[172] In an affidavit filed with the USPTO during the prosecution of the '302 Patent, a former Bard project engineer in the vascular access product area represented "that placement of a radiopaque marking on the surface of a port housing base was 'obvious to a person of ordinary skill in the art' and 'would have only involved ordinary creativity on behalf of the designer.'"[173]

Additionally, MedComp points to a 2001 news bulletin in Medical Industry Week, where Bard promoted the availability of its self-expanding nitinol biliary stent, which included

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[168] *Berkheimer*, 881 F.3d at 1369.

[169] *Electric Power*, 830 F.3d at 1354.

[170] *Berkheimer*, 881 F.3d at 1369.

[171] *See* Dkt. 463 at 15.

[172] *Id.*

[173] *Id.* at 15–16 (citing APP-08081 at ¶ 27).

radiopaque marker technology to allow for better visualization following placement of the stent within a patient.[174] MedComp argues that Bard's representations before the USPTO, along with Bard's statements to the press, support a finding that use of radiopaque identifiers is not an inventive concept unique to Bard's access port technology.[175]

Beyond Bard's own representations, MedComp also cites several articles from medical journals and industry publications discussing the use of radiographic marking on implantable medical devices years before Bard's asserted patents were issued. Specifically, the articles discuss the use of radiopaque identifiers to permit identification of implantable defibrillators, provide easy tracking and precise positioning of implantable stents, and allow for the detection of stray surgical swabs and sponges in post-operative patients.[176] According to MedComp, this evidence is incontrovertible proof "that the use of radiographic marking on implantable medical devices was routine and conventional at the time of the asserted Bard patents."[177]

In response, Bard points to the Federal Circuit's *AngioDynamics* decision in *Port II* to argue that MedComp's purported evidence "is insufficient to establish lack of inventive concept at *Alice* step two."[178] In *AngioDynamics*, the Federal Circuit found that the claims at issue in *Port II* were not solely directed to non-functional printed matter, and thus were not directed to patent ineligible subject matter under *Alice* step one.[179] However, the Federal Circuit explained that even if it "were to conclude that the sole focus of the claimed advance was the printed matter, AngioDynamics's evidence is not sufficient to establish as a matter of law, at *Alice* step

[174] *Id.* at 16 (citing APP-037).

[175] *Id.*

[176] *See id.* at 17–18.

[177] *Id.* at 18.

[178] Dkt. 534 at 38.

[179] *AngioDynamics*, 979 F.3d at 1384.

two, that the use of a radiographic marker, in the 'ordered combination' of elements claimed, was not an inventive concept."[180]

As previously explained, determining if a claim element "is well-understood, routine, and conventional to a skilled artisan in the relevant field is a question of fact."[181] As this court reads it, the Federal Circuit in *AngioDynamics* essentially reviewed and rejected, based on the record there provided, the trial court's factual finding that use of radiographic markings was routine and conventional in the art at the relevant time. Both the trial court's ruling and the Federal Circuit's evaluation were undoubtedly constrained by the evidence and arguments presented by the parties. But this court does not have before it the same record AngioDynamics's generated in *Port II*. The evidence and arguments submitted here by MedComp are considerably different. This court can only consider in the context of the arguments presented by the parties whether MedComp's evidence is sufficient to show that the use of radiopaque identifiers was well-understood, routine, and conventional at the time of the asserted Bard patents. The court concludes the evidence establishes exactly that.

In reviewing MedComp's evidence, it is clear that the application of radiopaque identifiers to subcutaneous medical devices was well-understood, routine, and conventional within the implantable medical device industry long before Bard decided to add the identifiers to its power-injectable ports. Indeed, Bard was already utilizing the technology on its own implantable stent products.[182] And by its own admission in the *Port III* case pending before

[180] *Id.*

[181] *Id.*

[182] *See* Dkt. 463 at 16.

Judge Nielson in this court, "Bard did not invent radiopaque markings on subcutaneous medical devices for identification by x-ray or other imaging."[183]

When analyzing the asserted claims individually, the use of a radiopaque identifier to convey information is not an inventive concept. Based on the evidence provided by MedComp, radiopaque identifiers were routinely used as information conveyors throughout the implantable medical device industry at the time of Bard's asserted patents. And when scrutinizing the asserted claims as an "ordered combination," the court still cannot find an inventive concept that transforms the claims into a patent-eligible application. Each of the claims begins with a typical access port made up of conventional features and then incorporates a radiopaque identifier into the port for the purpose of conveying its suitability for power injection. The addition of a non-functional radiopaque identifier to a known product is not an inventive concept. If the court were to hold otherwise, any medical device manufacturer would be able to add a radiopaque identifier to any commonly produced implantable medical product and—so long as they are the first to the patent office—claim a monopoly over an established product. Accordingly, the court finds that none of the asserted claims in the '302 and '022 Patents contain an inventive concept under *Alice* step two.

b. The Asserted Claim in the '615 Patent Does Not Contain an Inventive Concept

Identically to the specification for the '302 Patent, the specification for the '615 Patent explains that "the instant disclosure relates to an access port having at least one perceivable or identifiable feature for identifying the access port, wherein the identifiable feature is perceivable

[183] *See* Dkt. 593 (Memorandum Decision and Order Construing Disputed Claim Terms and Phrases) at 44, *C.R. Bard, Inc. et al. v. Medical Components, Inc.*, Case No. 2:17-cv-00754-HCN-DAO.

after the access port is implanted within a patient."[184] The '615 specification also teaches the "information of interest" communicated by the identifiable feature is that the "access port may be correlative with the access port being power injectable."[185] The specification then describes one embodiment of an access port, in which "at least one identifiable feature may be perceived by palpation (i.e., to examine by touch), by way of other physical interaction, or by visual observation."[186] This embodiment allows a "person of interest" to "touch or feel the access port through the skin to perceive at least one identifying characteristic thereof."[187]

Similar to its argument regarding the radiopaque identifiers in the '302 and '022 Patents, MedComp maintains here that the use of shape (referring to the required structural feature of one concave side surface in the asserted claim) is routine and conventional in the medical device field.[188] Bard does not respond to this argument. Rather, Bard advances in relation to the '615 Patent only an argument concerning *Alice* step one. Bard insists the focus of the claimed advance in the '615 Patent—a concave side that can be perceived by palpation after implantation—is not directed solely to content of the information conveyed but also to the means by which the information conveyed.[189] Having already rejected this argument in its preliminary inquiry to the *Alice* test, the court will not repeat here why that argument fails.

"When there is no genuine issue of material fact regarding whether the claim element or claimed combination is well-understood, routine, conventional to a skilled artisan in the relevant

[184] Dkt. 457-1, JA-149 at 3:62–65.

[185] *Id.* at 4:6–12.

[186] *Id.* at 4:17–19.

[187] *Id.* at 4:19–22.

[188] Dkt. 463 at 19.

[189] Dkt. 534 at 36.

field, this issue can be decided on summary judgment as a matter of law."[190] For the following two reasons, the court finds that the asserted claim in the '615 Patent does not contain an inventive concept.

First, the Federal Circuit has explained that to save a patent at *Alice* step two, "an inventive concept must be evident in the claims."[191] Here, Bard asserts only independent claim 8 of the '615 Patent. The claim language begins by describing the conventional features comprising the access port assembly, and then continues by requiring:

> at least one structural feature of the access port identifying the access port as being power injectable subsequent to subcutaneous implantation, the at least one structural feature comprising at least one concave side surface in a second side surface different from the first side surface, the concave side surface extending to the bottom perimeter concave portion.

Although the specification of the '615 Patent describes an embodiment of an access port wherein an identifiable feature may be perceived by a person through touch, the asserted claim does not recite this alleged innovation. Indeed, the claim language completely fails to describe how a person may utilize the "one structural feature" to determine any identifying information about the port. "The main problem that [Bard] cannot overcome is that the *claim*—as opposed to something purportedly described in the specification—is missing an inventive concept."[192]

Second, the evidence presented by MedComp establishing the use of shape identifiers in the medical device field is persuasive. MedComp provides articles and charts from medical journals dating between 1969 to 2019, describing the use of shape to differentiate between the brand and type of implanted pacemakers.[193] While the articles do not address the innovation of

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[190] *Berkheimer*, 881 F.3d at 1368.

[191] *Two-Way Media*, 874 F.3d at 1338.

[192] *Id.* (emphasis in original).

[193] *See* Dkt. 463 at 19–22.

using palpation in conjunction with the shape of the medical devices, it is clear that utilizing a device's shape to convey information is not a new concept. Consequently, in analyzing the asserted claim language under *Alice* step two, the court finds that claim 8 of the '615 Patent does not contain an inventive concept.

Because the claims at issue are directed to the ineligible abstract idea of communicating information and lack an inventive concept, the court holds that asserted claims 1, 3, 4, 5, 6, 7, 8 and 10 of the '302 Patent, asserted claims 1, 3, 5, 8, 9, 10, 12, and 14 of the '022 Patent, and asserted claim 8 of the'615 Patent are invalid under § 101.

CONCLUSION

For the foregoing reasons, Defendant's Motion for Partial Summary Judgment is GRANTED IN PART on the grounds of invalidity.[194]

SO ORDERED this 22nd day of July 2021.

BY THE COURT:

ROBERT J. SHELBY
Chief United States District Judge

[194] Dkt. 463.